

Appln No.: 09/944,389  
Amendment Dated: May 26, 2004  
Reply to Office Action of June 20, 2003

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1-25. (canceled)

26. (previously presented) A device for detection of an analyte in a liquid sample, comprising a housing, having disposed therein:

- (a) a dry porous carrier;
- (b) an immobilized specific binding reagent which binds specifically to the analyte, said immobilized specific binding reagent being immobilized in a detection zone on or in the dry porous carrier;
- (c) a labeled specific binding reagent comprising a particulate label portion and a binding portion specific for the analyte, wherein said labeled specific binding reagent and said immobilized specific binding reagent combine with analyte, if present, to form an immobilized and directly-detectable product in the detection zone; and
- (d) a macroporous body disposed such that a liquid sample applied to the macroporous body will flow along a flow path extending from the macroporous body and into the dry porous carrier at a location separated from the detection zone, wherein the macroporous body contains the labeled specific binding reagent, said labeled specific binding reagent being freely mobile within the macroporous body when the macroporous body is wetted with the liquid sample.

27. (previously presented) The device according to claim 26, wherein the particulate label is selected from the group consisting of coloured latex particles, gold sols, non-metallic colloids and dye sols.

28. (previously presented) The device of claim 26, wherein the macroporous body has a pore size which is at least 10 times greater than the maximum particle size of the particulate label.

29. (previously presented) The device of claim 26, wherein the macroporous body has a pore size of not less than 10 microns.

30. (previously presented) The device of claim 26, wherein the macroporous body has a pore size of about 100 microns.

Appln No.: 09/944,389  
Amendment Dated: May 26, 2004  
Reply to Office Action of June 20, 2003

31. (previously presented) The device of claim 26, wherein particulate labels have a maximum diameter of about 0.5 microns.
32. (previously presented) The device of claim 26, wherein the dry porous carrier is a chromatographic strip.
33. (previously presented) The device of claim 32, wherein the dry porous carrier is formed from nitrocellulose.
34. (previously presented) The device of claim 26, wherein the macroporous body is in direct moisture-conductive contact with the dry porous carrier.
35. (previously presented) The device of claim 34, wherein the macroporous body has a liquid capacity which is at least equal to the liquid capacity of the working portion of the dry porous carrier, said working portion extending from the location where the flow path enters the dry porous carrier to the detection zone.
36. (previously presented) The device of claim 26, further comprising a porous sample receiving member, said sample receiving member being disposed along the flow path such that a sample applied to the sample receiving member flows sequentially from the sample receiving member, through the macroporous body and into the dry porous carrier.
37. (previously presented) The device of claim 36, wherein the sample receiving member extends from the inside of the housing to the exterior of the housing.
38. (previously presented) The device of claim 37, further comprising a removable cap or shroud disposed over the portion of the sample receiving member which is exterior to the housing.
39. (previously presented) The device of claim 26, wherein the housing has an aperture formed therein for observation of the detection zone.
40. (previously presented) The device of claim 26, wherein the immobilized reagent is impregnated throughout the dry porous carrier in the detection zone.
41. (previously presented) The device of claim 26, wherein the labeled specific binding reagent and the immobilized specific binding reagent each comprise an analyte-specific antibody.
42. (previously presented) The device of claim 26, further comprising a non-specific control reagent disposed in a control zone of the dry porous carrier, said control reagent capturing the

Appln No.: 09/944,389  
Amendment Dated: May 26, 2004  
Reply to Office Action of June 20, 2003

labeled specific binding reagent to produce a detectable product in the control zone in the presence or absence of analyte in an applied sample.

43. (previously presented) The device of claim 26, wherein the macroporous body comprises a plastic material.

44. (previously presented) The device of claim 26, wherein the device further comprises a second immobilized specific binding reagent which binds specifically to a second analyte, said second immobilized specific binding reagent being immobilized in a second detection zone on or in the dry porous carrier; and a second labeled specific binding reagent comprising a particulate label portion and a binding portion specific for the second analyte, wherein said second labeled specific binding reagent and said second immobilized specific binding reagent combine with the second analyte, if present, to form an immobilized and directly-detectable product in the second detection zone, said second labeled specific binding reagent being contained in the macroporous body.

45. (previously presented) The device of claim 26, wherein the analyte is human chorionic gonadotropin (hCG), and the immobilized specific binding reagent and the labeled specific binding reagent each bind to hCG.

46. (previously presented) The device according to claim 45, wherein the particulate label is selected from the group consisting of coloured latex particles, gold sols, non-metallic colloids and dye sols.

47. (previously presented) The device of claim 45, wherein the macroporous body has a pore size which is at least 10 times greater than the maximum particle size of the particulate label.

48. (previously presented) The device of claim 45, wherein the macroporous body has a pore size of not less than 10 microns.

49. (previously presented) The device of claim 45, wherein the macroporous body has a pore size of about 100 microns.

50. (previously presented) The device of claim 45, wherein particulate labels have a maximum diameter of about 0.5 microns.

51. (previously presented) The device of claim 45, wherein the dry porous carrier is a chromatographic strip.

Appln No.: 09/944,389

Amendment Dated: May 26, 2004

Reply to Office Action of June 20, 2003

52. (previously presented) The device of claim 51, wherein the dry porous carrier is formed from nitrocellulose.

53. (previously presented) The device of claim 45, wherein the macroporous body is in direct moisture-conductive contact with the dry porous carrier.

54. (previously presented) The device of claim 53, wherein the macroporous body has a liquid capacity which is at least equal to the liquid capacity of the working portion of the dry porous carrier, said working portion extending from the location where the flow path enters the dry porous carrier to the detection zone.

55. (previously presented) The device of claim 45, further comprising a porous sample receiving member, said sample receiving member being disposed along the flow path such that a sample applied to the sample receiving member flows sequentially from the sample receiving member, through the macroporous body and into the dry porous carrier.

56. (previously presented) The device of claim 55, wherein the sample receiving member extends from the inside of the housing to the exterior of the housing.

57. (previously presented) The device of claim 56, further comprising a removable cap or shroud disposed over the portion of the sample receiving member which is exterior to the housing.

58. (previously presented) The device of claim 45, wherein the housing has an aperture formed therein for observation of the detection zone.

59. (previously presented) The device of claim 45, wherein the immobilized reagent is impregnated throughout the dry porous carrier in the detection zone.

60. (previously presented) The device of claim 45, wherein the labeled specific binding reagent and the immobilized specific binding reagent each comprise an analyte-specific antibody.

61. (previously presented) The device of claim 45, further comprising a non-specific control reagent disposed in a control zone of the dry porous carrier, said control reagent capturing the labeled specific binding reagent to produce a detectable product in the control zone in the presence or absence of analyte in an applied sample.

62. (previously presented) The device of claim 45, wherein the macroporous body comprises a plastic material.

Appln No.: 09/944,389  
Amendment Dated: May 26, 2004  
Reply to Office Action of June 20, 2003

63. (previously presented) The device of claim 45, wherein the device further comprises a second immobilized specific binding reagent which binds specifically to a second analyte, said second immobilized specific binding reagent being immobilized in a second detection zone on or in the dry porous carrier; and a second labeled specific binding reagent comprising a particulate label portion and a binding portion specific for the second analyte, wherein said second labeled specific binding reagent and said second immobilized specific binding reagent combine with the second analyte, if present, to form an immobilized and directly-detectable product in the second detection zone, said second labeled specific binding reagent being contained in the macroporous body.

64. (previously presented) The device of claim 26, wherein the analyte is luteinizing hormone(LH), and the immobilized specific binding reagent and the labeled specific binding reagent each bind to LH.

65. (previously presented) The device according to claim 64, wherein the particulate label is selected from the group consisting of coloured latex particles, gold sols, non-metallic colloids and dye sols.

66. (previously presented) The device of claim 64, wherein the macroporous body has a pore size which is at least 10 times greater than the maximum particle size of the particulate label.

67. (previously presented) The device of claim 64, wherein the macroporous body has a pore size of not less than 10 microns.

68. (previously presented) The device of claim 64, wherein the macroporous body has a pore size of about 100 microns.

69. (previously presented) The device of claim 64, wherein particulate labels have a maximum diameter of about 0.5 microns.

70. (previously presented) The device of claim 64, wherein the dry porous carrier is a chromatographic strip.

71. (previously presented) The device of claim 70, wherein the dry porous carrier is formed from nitrocellulose.

72. (previously presented) The device of claim 64, wherein the macroporous body is in direct moisture-conductive contact with the dry porous carrier.

Appln No.: 09/944,389  
Amendment Dated: May 26, 2004  
Reply to Office Action of June 20, 2003

73. (previously presented) The device of claim 72, wherein the macroporous body has a liquid capacity which is at least equal to the liquid capacity of the working portion of the dry porous carrier, said working portion extending from the location where the flow path enters the dry porous carrier to the detection zone.

74. (previously presented) The device of claim 64, further comprising a porous sample receiving member, said sample receiving member being disposed along the flow path such that a sample applied to the sample receiving member flows sequentially from the sample receiving member, through the macroporous body and into the dry porous carrier.

75. (previously presented) The device of claim 64, wherein the sample receiving member extends from the inside of the housing to the exterior of the housing.

76. (previously presented) The device of claim 75, further comprising a removable cap or shroud disposed over the portion of the sample receiving member which is exterior to the housing.

77. (previously presented) The device of claim 64, wherein the housing has an aperture formed therein for observation of the detection zone.

78. (previously presented) The device of claim 64, wherein the immobilized reagent is impregnated throughout the dry porous carrier in the detection zone.

79. (previously presented) The device of claim 64, wherein the labeled specific binding reagent and the immobilized specific binding reagent each comprise an analyte-specific antibody.

80. (previously presented) The device of claim 64, further comprising a non-specific control reagent disposed in a control zone of the dry porous carrier, said control reagent capturing the labeled specific binding reagent to produce a detectable product in the control zone in the presence or absence of analyte in an applied sample.

81. (previously presented) The device of claim 64, wherein the macroporous body comprises a plastic material.

82. (previously presented) The device of claim 64, wherein the device further comprises a second immobilized specific binding reagent which binds specifically to a second analyte, said second immobilized specific binding reagent being immobilized in a second detection zone on or in the dry porous carrier and a second labeled specific binding reagent comprising a particulate label portion and a binding portion specific for the second analyte, wherein said second labeled specific binding reagent and said second immobilized specific binding reagent combine with the

Appln No.: 09/944,389

Amendment Dated: May 26, 2004

Reply to Office Action of June 20, 2003

second analyte, if present, to form an immobilized and directly-detectable product in the second detection zone, said second labeled specific binding reagent being contained in the macroporous body.

83. (previously presented) The device of claim 26, further comprising a second dry porous carrier strip arranged such that the flow path extends from the macroporous body into both carrier strips, in parallel, said second carrier strip having a binding reagent immobilized thereon or therein, said binding reagent on the second porous strip being selected from binding reagents specific for the analyte and binding reagents specific for a different material of interest.

84. (previously presented) A device for analyzing a liquid sample suspected of containing an analyte, comprising a housing, having disposed therein:

- (a) a porous carrier comprising a detection zone;
- (b) a capture reagent effective to capture analyte in the detection zone, said capture occurring after the liquid sample has been applied to the device if said analyte is present in the liquid sample;
- (c) a labeled binding reagent comprising a particulate label portion and a binding portion, wherein said labeled binding reagent and said capture reagent combine with analyte, if present, to form an immobilized and directly-detectable product in the detection zone; and
- (d) a macroporous body disposed such that a liquid sample applied to the macroporous body will flow along a flow path extending from the macroporous body and into the porous carrier at a location separated from the detection zone, wherein the macroporous body contains the labeled binding reagent, said labeled specific binding reagent being freely mobile within the macroporous body when the macroporous body is wetted with the liquid sample, and wherein the capture reagent, the analyte and the labeled binding reagent form an immobilized complex in the detection zone when the analyte is present in the liquid sample applied to the device.

85. (previously presented) The device of claim 84, wherein the capture reagent is an analyte-specific antibody immobilized in the detection zone.

86. (previously presented) The device of claim 84, wherein the porous carrier is nitrocellulose.

87. (currently amended) In a device for detection of an analyte in a sample, in which a liquid sample is applied to a porous carrier comprising a detection zone and a sandwich complex is formed in the detection zone when analyte is present, said porous carrier being disposed within

Appln No.: 09/944,389

Amendment Dated: May 26, 2004

Reply to Office Action of June 20, 2003

a housing, and said sandwich complex comprising a labeled binding reagent, the analyte and an immobilized capture reagent, the improvement wherein the device further comprises a macroporous body disposed such that a liquid sample applied to the macroporous body will flow along a flow path extending from the macroporous body and into the porous carrier at a location separated from the detection zone, wherein the macroporous body contains the labeled binding reagent, said labeled binding reagent being freely mobile within the macroporous body when the labeled binding reagent in the macroporous body is wetted with the liquid sample.

88. (canceled)

89. (previously presented) The device of claim 84, further comprising a porous sample receiving member, said sample receiving member being disposed along the flow path such that a sample applied to the sample receiving member flows sequentially from the sample receiving member, through the macroporous body and into the dry porous carrier.

90. (previously presented) The device of claim 89, wherein the sample receiving member extends from the inside of the housing to the exterior of the housing.

91. (previously presented) The device of claim 84, wherein the analyte is human chorionic gonadotropin (hCG), and the capture reagent and the labeled binding reagent each bind to hCG.

92. (previously presented) The device of claim 84, wherein the macroporous body has a liquid capacity which is at least equal to the liquid capacity of the working portion of the dry porous carrier, said working portion extending from the location where the flow path enters the dry porous carrier to the detection zone.

93. (previously presented) The device of claim 84, wherein the macroporous body and the porous carrier each have two major surfaces and wherein the flow path is substantially planar and parallel to the major surfaces of macroporous body and the porous carrier.

94. (previously presented) The device of claim 93, wherein the macroporous body and the porous carrier overlap at their adjacent ends.

95. (previously presented) The device of claim 84, further comprising a non-specific control reagent disposed in a control zone of the dry porous carrier, said control reagent capturing the labeled binding reagent to produce a detectable product in the control zone in the presence or absence of analyte in an applied sample.



Appln No.: 09/944,389  
Amendment Dated: May 26, 2004  
Reply to Office Action of June 20, 2003

96-102. (canceled)